Johari Digital Healthcare Ltd.

ISO 13485 : 2003; 9001 : 2000, FDA USA Regd.

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Traditional 510(k) - K062439

ANNEXURE 'VIII'

SUMMARY

JAN - 8 2007

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"Traditional 510(k) summary"

Submitter's Name	:	Nisha Johari
Title	:	Director Marketing JOHARI HEALTH CARE LTD. Electronic Hardware Technology Park G-582, 583 E.P.I.P., Boranada, Jodhpur 342008
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E-mail	:	joharicare@sify.com
Contact person	:	Pooja Johari
Date of summary is submitted	:	August 16,2006
Resubmitting on	:	November 23,2006

8.1

Nisha Johari.

Traditional 510(k) - K062439 **ANNEXURE 'VIII'**

NEW DEVICE FOR WHICH SUBMITTING

Trade Name	:	**Powertone**
Model No.	:	**PT-11**
Common Name	:	**Muscle Stimulator**
Classification Name	:	**Physical Medicine (Per 21 CFR section 890.5850)**

LEGALLY MARKETING DEVICE

Slendertone Flex BT	:	Toning and Firming – bottoms/thighs
Manufacturer	:	BIO-MEDICAL RESEARCH Ltd.
Address	:	BMA HOUSE, PARKMORE BUSINESS PARK WEST, GALWAY, IRELAND
Slendertone Flex Max	:	Abdominal Training System
Manufacturer	:	BIO-MEDICAL RESEARCH Ltd.
Address	:	BMA HOUSE, PARKMORE BUSINESS PARK WEST, GALWAY, IRELAND
Phone	:	+353 91 774361
Fax	:	+353 91 773302

DESCRIPTION OF NEW DEVICE POWERTONE

Powertone is a Muscle stimulator with two different outputs. This battery powered unit is designed for men & women to provide exercise technology anytime-whether relaxing at home or to use as a part of exercise routine .The stimulation is the most comfortable & this technology makes it easier to combine active & passive exercise.

PT-11 stimulator provides selections of different programs through one output to treat Abdominal muscles (ABS) & through two outputs Bottom /Thighs muscles (BTS). Four body areas can be treated. LCD shows the selected program & balance treatment time.

The MKB panel with the LCD simplifies the selections. This unit is ergonomically designed, being portable it is easy and simple to use, yet works as a Clinical model (two output channels) rechargeable batteries power it. The unit can perform anytime & anywhere. Powertone is suitable for use by all healthy adults. However as with other form of exercise, some care is needed when using them. The electrical muscle stimulator (Powertone) contracts muscles rhythmically to achieve muscle tone and strength. This unit contains six self-adhesive electrodes, which can be fixed to the belt with buttons.

Powertone comes complete with all the necessary component to perform Muscle stimulation Below is a list of items that are included:

		Quantity
1.	POWERTONE unit	01
2.	Electrode cables (3 pole)	02
3.	a) Elastic belt short style	01
	b) ABS Belt	01
4.	Charger	01
5.	Rechargeable Battery (AA, Ni-MH)	04
6.	Instruction Manual	01
7.	Carry bag	01
8.	Electrodes-	
	Large(50 mm)	02
	Small (40 X 80mm)	04

INFORMATION ABOUT CHARGER

- The Main unit is designed to work only on Battery and the charger is provided to charge the batteries.
- Plug the DC jack of the charger into DC power socket of the main unit.
- Plug the charger into an AC mains socket.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nisha Johari
Johari Digital Healthcare, Ltd.
C/O Better Life Device Corporation
26540 W. Agoura Road, Suite 230
Calabases, California 91302

JAN - 8 2007

Re: K062439
Trade/Device Name: Powertone PT-11
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 23, 2006
Received: November 30, 2006

Dear Mrs. Johari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

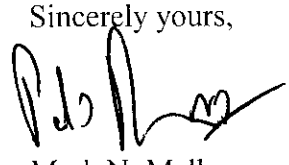
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062439

Device Name: Powertone-PT-11

Indications For Use:

POWERTONE PT-11 is intended to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of a firmer abdomen.
- Strengthening, toning and firming of buttocks & thigh

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062439